Appl. No.: 10/695,295
Amdt. dated December 16, 2005
Reply to Office action of November 2, 2005

REMARKS/ARGUMENTS

Claims 1 – 25 are pending in the Application. Claims 11 – 25 haven been withdrawn from consideration.

Claims 1 and 3 – 10 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,360,417 to Gravener et al. Applicants respectfully traverse these rejections because Gravener et al. do not disclose the claimed invention.

To be anticipating, a prior art reference must disclose each and every limitation of the claimed invention. More particularly, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, *arranged as in the claim*." Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Found. v. Genentech Inc., 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

Claim 1 of the present Application includes a "surgical valve having an axis extending between a proximal and a distal end, comprising:

"a housing including a proximal housing portion and a distal housing portion cooperating with the proximal housing portion to define a gel cavity;

"a seal material disposed in the gel cavity, the seal material including a gel having non-compressible characteristics;

"a proximal guide tube extending axially proximally from the proximal housing

portion; the proximal guide tube facilitating insertion of a surgical instrument into the seal material;

"a distal guide tube extending axially distally from the distal housing portion, the distal guide tube facilitating retrograde insertion of the surgical instrument into the surgical seal."

The Examiner indicates that Gravener et al. disclose the elements of Applicants' claim 1, including "the proximal guide tube facilitating insertion of a surgical instrument into the seal material." (Emphasis added.) As depicted in FIGS. 6 and 7 of the present Application, the seal material (81a) includes a channel (101a). The channel (101a) is formed into the seal material (81a). (See Application, page 12, lines 4-5 and page 13, lines 9-10.) No intervening material is described or shown disposed in the channel (101a) in the seal material (81a), as is the case with the "channel" in the seal material of Gravener et al. Hence, when a surgical instrument is inserted into the surgical valve claimed in Applicants' Claim 1, the surgical instrument is inserted into the seal material and is in actual contact with the seal material. When a surgical instrument is inserted into Gravener et al.'s surgical valve, the surgical instrument is passed through a sleeve of the middle portion (28) of the body (12), as depicted in FIG. 8 in Gravener et al., and never comes into actual contact with the seal material. Gravener et al. do not depict or describe the surgical instrument being inserted into the seal material.

The Examiner also indicates that Gravener et al. disclose, as in Applicants' Claim 1, "a distal guide tube extending axially distally from the distal housing portion...."

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FIG. 6 of the present Application depicts a distal tube (85a) extending distally from a distal housing (76a). The Examiner indicated that item 18 of Gravener et al. is the distal housing portion, but nowhere in Gravener et al. is there depicted or described a corresponding distal guide tube that extends distally from the distal housing portion. Additionally, The Examiner indicates in the Rejection that Gravener includes "a distal guide tube (22) ..." (emphasis added), however, throughout the remainder of the Rejection item (22) refers to a "proximal guide tube." Moreover, Gravener et al., at column 5, line 29, indicates that item 22 is a "proximal opening." Based on the foregoing, Applicants respectfully submit that Claim 1 is allowable over Gravener et al. because Gravener et al. do not disclose nor suggest each and every feature of the Applicants' claim 1. As independent Claim 1 is allowable, dependent claims 2-4 are also allowable.

Claim 6 of the present Application includes a "surgical valve, comprising:

"a first housing portion defining a gel cavity;

"a seal material including a gel and having a node and an axial channel;

"a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state; and

"a second housing portion disposed in juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state."

The Examiner indicates that Gravener et al. disclose the elements of Applicants'

claim 6, including a "node" (32). As stated above, Applicants' Claim 6 includes a "seal material including a gel and having a node...." As shown in FIG. 6 of the present Application, item (81a) is the seal material including a gel having a node 116. The node 116 is part of the seal material (81a). The gel seal material of Gravener et al. does not include a corresponding "node." The "node" referred to by the Examiner in Gravener et al. is part of the "proximal housing portion" (26) and not part of the gel seal material.

The Examiner also indicated that Gravener et al. include the element of Applicants' Claim 6 of a "subassembly including the seal material disposed in the gel." What Applicants' Claim 6 actually includes is "a first housing portion defining a gel cavity; a seal material ...; [and] a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state...." The gel cavity is defined by the first housing portion and the subassembly includes the seal material being disposed in the gel cavity. Thus, the subassembly includes the first housing portion with the seal material disposed in the gel cavity. Gravener et al. do not disclose or teach any corresponding features of Applicants' Claim 6. The first (distal) and second (proximal) housing portions of Gravener et al. are integral to each other. When the seal material is added to the gel cavity (42), as in FIGS. 6 and 7 of Gravener et al., then the valve assembly is complete; there is no "subassembly" including the first housing portion and the seal material.

The Examiner also indicated that Gravener et al. include the element of Applicants' Claim 6 of "a second housing portion disposed in juxtaposition to the first

housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state." The Examiner refers Applicants to Gravener et al.'s FIG. 9 for this element. FIG. 9 of Gravener et al. does not depict the seal material in a closed state, but instead depicts an instrument (44) being withdrawn from the valve (12), permitting the seal material to approach a closed state.

As stated above, Claim 6 includes a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state; it is the force applied to the seal material by the second housing portion that places the channel in a closed state. In the Rejection, the Examiner indicated that in Gravener et al. the "seal material [is] configured with the channel in an open state." If the Examiner contends that FIG. 7 of Gravener et al. depicts the channel in an open state, then Applicants respectfully submit that the channel of Gravener et al. is never in a closed state as Gravener et al. do not teach the channel being closed any further than as depicted in FIGS. 6 and 7. Alternatively, if the Examiner contends that FIGS. 8 and/or 9 of Gravener et al. depict the channel in an open state, then Applicants respectfully submit that the seal material of Gravener et al. is not configured with the channel in an open state. In this scenario, it appears that the instrument (44) of Gravener et al. places the channel in the open state. Additionally, as described in Gravener et al. (column 4, lines 64-66), the "gel 42 fills cavity 40 and provides longitudinal and radial pressure about the aperture 14 (FIG. 3). The gel 42 biases the

middle portion 28 of aperture 14 closed...." Hence, in Gravener et al., it is pressure from the gel that places the channel in a closed state, not a force applied by the second (proximal) housing portion. Based on the foregoing, Applicants respectfully submit that Claim 6 is allowable over Gravener et al. because Gravener et al. do not disclose nor suggest each and every feature of the Applicants' claim 6. As independent Claim 6 is allowable, dependent claims 7-9 are also allowable.

Claim 10 of the present Application includes a "surgical valve adapted to form a seal around a surgical instrument extending through the valve, comprising:

"a first housing portion;

"a second housing portion engaging the first housing portion and defining with the first housing portion a gel cavity having a volume;

"a gel disposed within the gel cavity and having properties including flowability and incompressibility, the gel having characteristics for creating a pressure on the instrument to form a seal with the instrument; and

"means for moving the second housing portion relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve." (Emphasis added.)

The Examiner indicates that Gravener et al. disclose the elements of Applicants' claim 10, including "means for moving the second housing portion relative to the first housing portion to increase the pressure of the incompressible gel on the instrument

and to create a locking force tending to inhibit movement of the instrument relative to the valve." The Examiner directs Applicants to Gravener et al. column 4, line 64. That portion of Gravener et al. refers to the gel (42) biasing the middle portion (28) of aperture (14) closed to prevent gases and fluids from escaping through the body (12) when no instrument is present in the valve assembly (10). However, that portion of Gravener et al. does not teach anything about means for moving the second housing portion relative to the first housing portion to increase pressure of the gel on the instrument to create a "locking force" to inhibit movement of the instrument relative to the valve. While it may be inherent that the presence of an instrument within the aperture (14) of Gravener et al. may increase pressure of the gel, Gravener et al. teach the passage of an instrument through the aperture (14) while providing a seal around the instrument passing therethrough (see Gravener et al. column 5, lines 1-5), but does not teach the force being sufficient to create a locking force to inhibit movement of the instrument. The present Application teaches the increased pressure of the seal material reducing the channel through the seal material, causing the seal material to compress upon an instrument inserted therethrough and tending to lock the instrument in place relative to the valve. (See Application page 14, line 18 through page 16, line 3.) Based on the foregoing, Applicants respectfully submit that Claim 10 is allowable over Gravener et al. because Gravener et al. do not disclose nor suggest each and every feature of the Applicants' claim 10.

Claim 2 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over

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U.S. Patent No. 5,360,417 to Gravener et al. in view of U.S. Patent No. 5,514,109 to Mollenauer et al. Applicants respectfully traverse this rejection because Gravener et al. do not disclose the claimed invention and Mollenauer et al. do nothing to correct the deficiencies. As stated above, Gravener et al. fail to teach all of the elements of independent Claim 1. Dependent Claim 2 includes a Luer lock being coupled to the distal housing portion and the distal guide tube being included within the Luer lock. As stated above, Gravener et al. do not teach a distal guide tube extending distally from the distal housing portion. Moreover, Gravener et al. teach the valve being housed within a housing, the distal end of the housing having a neck (64) with an aperture (65) dimensioned for reception of an appropriate tube such as a cannula (66) (see Gravener et al. FIG. 20 and column 6, line 67 trough column 7, line 12).

In order to combine the reference, there must be some suggestion or motivation in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. See MPEP § 2142. Applicant respectfully submits that nothing in Gravener et al. would suggest a combination of the valve of Gravener et al. with a Luer lock positioned on its distal end because the valve of Gravener et al. is configured to mount within a valve housing and the valve housing includes means for attaching to other devices. Moreover, the valve assembly (10) includes a wall plate (24) positioned toward the proximal end of the valve assembly. The valve housing includes a partition (72) that holds the proximal end of the valve assembly (10) in position at the wall plate (24). The purpose of the wall plate

(24) is to facilitate housing the valve assembly (10) within the valve housing. With the wall plate (24) being depicted in every embodiment of Gravener et al., it is not contemplated that the valve assembly of Gravener et al. would ever be used absent the valve housing.

Furthermore, there must be a reasonable expectation of success. The combination of Gravener et al. and Mollenauer et al. provides no reasonable expectation of success since the valve assembly of Gravener et al. in housed within a valve housing and the valve housing includes the means for attaching to other devices. Applicants respectfully submit that there is no reasonable expectation that the addition of a Luer lock to the distal end of the valve assembly of Gravener et al. would provide successful results with the valve assembly positioned within the valve housing having means for attaching to other devices.

Lastly, the combination must teach or suggest all the claim limitations. See MPEP §2143.03. As discussed above, Gravener et al. does not include a distal guide tube extending distally from the distal housing portion. Mollenauer et al. do nothing to correct this deficiency. Further, neither Gravener et al. nor Mollenauer et al., either alone or in combination, teach the Luer lock being coupled to the distal housing portion and the distal guide tube being included within the Luer lock. Based on the foregoing, Applicants respectfully submit that dependent claim 2 is allowable over Gravener et al. in view of Mollenauer et al.

Based on foregoing remarks, Applicants respectfully submit that all pending

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claims are in condition for allowance and earnestly solicit a notice thereof. Applicants encourage the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the Application.

Sincerely

APPLIED MEDICAL RESOURCES

BY _____

David G. Majdali
Reg. No. 53,257
Tel: (949) 713-8233